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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 14

Application Number: 09/769,970
Filing Date: January 24, 2001
Appellant(s): Bandman et al.

Susan K. Sather
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 3, 2003

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 24, 27-29, and 31 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 27-29, and 31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2. The specification does not teach polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function. Without a statement regarding the activity of a

polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2 or polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function one skilled in the art cannot know the metes and bounds of the claimed polynucleotides. For example, the claims encompass inactive and/or antagonist kinases, and the like. Therefore, there is no functional parameter of activity for these polynucleotides and therefore the claims lack written description.

(11) Response to Argument

Claims 24, 27-29, and 31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Appellants urge from pages 3-5 that the Examiner has ignored the limitation that the claimed polynucleotides encodes a polypeptide comprising a naturally occurring amino acid sequence, or comprise a naturally occurring polynucleotide sequence and has attempted to introduce functional limitations into these claims where no functional limitation is present. As noted in the rejection, without a statement regarding the activity of the polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2 or polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function one skilled in the art cannot know the metes and bounds of the claimed polynucleotides. Appellants have not described these polynucleotides, whether naturally occurring or not. If Appellants desire a variant of a polynucleotide encoding SEQ ID NO: 2 or having SEQ ID NO: 9, then functional language will be placed into the claim so that one skilled in the art has an assayable activity to determine if their polynucleotides is anticipated by Appellants. Appellants are referred to Example 14 of the Written Description Guidelines. Note that DAPK-2 is a deduced amino acid sequence and that it's kinase activity decided by sequence homology to VRK1 (page 18 and

Example III at page 50). The potential to assess kinase activity is prophetically taught in Example X at page 56). Therefore, the specification does not teach polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2 or polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function.

In their arguments, Appellants refer to DAPK-2, or disease associated protein kinase-2, and state that chemical and structural features of DAPK-2 are described in the specification (page 4, last para). Note that the name of the protein, which in itself provides function, is not used in the claims. While the specification describes polynucleotides encoding a polypeptide having 90% sequence identity to SEQ ID NO: 2 or having at least 90% sequence identity to SEQ ID NO: 9 and being a disease associated protein kinase, the specification does not provide written description for polynucleotides encoding a polypeptide having 90% sequence identity to SEQ ID NO: 2 or having at least 90% sequence identity to SEQ ID NO: 9 because there is no correlation of structure with function.

In Argument A, Appellants discuss *Fiers* and *Lilly* at pages 5 and 6. At page 7, Appellants attempt to define their claim language over *Fiers* and *Lilly* and state that the Final Office Action failed to provide an appropriate analysis of the present claims and how they differ from those found not to satisfy the written description requirement in *Fiers* and *Lilly*. The Examiner is not charged with comparing and contrasting claims under examination with claims found in case law. Rather, the Examiner analyzes the claims with respect to the statute with the aid of the written description guidelines that she has been provided. In *Fiers* and in *Lilly*, function without structure was provided. In the instant claims, structure without function is provided. The written description guidelines at Example 14 specifically require that both structure and function will be provided when a variant of a polypeptide (or other compound) is claimed. Thus, the instant claims lack written description.

In Argument B, Appellants state that the claims do not describe a genus which could be characterized as highly variant and discuss new references, Brenner et al. and Hegyi et al. without benefit of making these references official by filing them with an Information Disclosure Statement (PTO- 1449). The Examiner is not questioning that one skilled in the art can use sequence homology to predict activity. In the Final Rejection, the Examiner has agreed with this statement:

> Note that DAPK-2 is a deduced amino acid sequence and that it's kinase activity decided by sequence homology to VRK1 (page 18 and Example III at page 50). The potential to assess kinase activity is prophetically taught in Example X at page 56).

Indeed, polynucleotides encoding SEQ ID NO: 2 or having SEQ ID NO: 9 is allowable because these sequences have been associated with function, even if by sequence homology. Variations of these structures without recitation of the kinase or any other function lacks written description.

In Argument C at page 9, Appellants believe that the state of the art at the time of the present invention is further advanced that at the time of *Fiers* and *Lilly*. The claims were not rejected from enablement but for lack of written description. Therefore, this argument does not appear to be germane to the instant rejection of the claims.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Karen Cochrane Carlson Ph.D

November 12, 2003

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